

REMARKS/ARGUMENTS

Reconsideration of the present application, as amended, is respectfully requested.

A. Status of the Claims and Claim Amendments

As a result of the present amendment, claims 1, 3-18 and 20-24 are presented for further prosecution. Claims 2 and 19 have been cancelled.

Claims 1 and 14 have been amended by this amendment to include a further limitation that the core is film coated. Support for these amendments can be seen, for example, from cancelled Claim 2.

Claim 5 has been amended to change its dependency to Claim 1.

Claims 8 and 20 have been amended to correct an obvious typographical error.

Claim 22 has been amended to point out the ink to be an ingestible and pharmaceutically acceptable ink. Support to this amendment can be seen, for example, in the first paragraph of page 6 of the specification.

No new matter was added by the amendments.

B. Claims Rejection under 35 U.S.C. § 112

The Examiner rejected Claim 22 for using trademark Opacode.

Claim 22 has been amended to delete trademark Opacode and define the ink to be ingestible and pharmaceutically acceptable, as disclosed in the first paragraph of page 6 of the specification.

It is believed that Claim 22 is now definite and free of the § 112 deficiency.

C. Claims Rejections under 35 U.S.C. § 103

The Examiner rejected the subject matter of claims 1-8, 11- 21, 23 and 24 as being unpatentable over Nellhaus in view of Sullivan; rejected Claim 9 over Nellhaus and Sullivan in view of Siegel; rejected Claim 10 over Nellhaus in view of Johnson; and rejected Claim 22 over Nellhaus and Sullivan in view of Cruttenden.

Applicants note that the Examiner has rejected the subject matter related to a “film coated core” in claims 2 and 19 based on Nellhaus in view of Sullivan. Applicants have cancelled claims 2 and 19, and incorporated the limitations into claims 1 and 14. For the following reasons, it is respectfully submitted that Sullivan does not teach the “core is film coated prior to said printed or etched marking being applied thereto” as in Claims 1 and 14.

1. Sullivan’s “code-receiving layer” is not a film coated on the pill.

The Examiner rejected Claim 2, citing the disclosure in Sullivan at column 11, line 36 to column 12, line 43. The Examiner asserts: “Sullivan teaches a barcode is printed on a label of a pill, which has a code-receiving layer (a core portion) that has a film (a protein based film) coated prior to the printed being applied thereto.”

A thorough reading of Sullivan shows that the “film” mentioned in above citation refers to a labeling “carrier”, which covers only a part of the core rather than a film coating applied to the entire core substrate. The following teachings in Sullivan support this position (see 2nd paragraph of column 12):

“The code pattern is either printed directly on the pill, or is first printed on a carrier or code-receiving layer, as described above, such as paper, thin plastic film (e.g., PVOH or EVOH), a protein-based material, such as gelatin and keratin film or related collagen-based films, or a biocompatible polymeric sheet or film. The carrier is then preferably applied to the pill during the manufacturing process, as described above, or at a later time, perhaps by a doctor, nurse, or pharmacist, depending on the specific application of the invention.”

Clearly, the “film” in Sullivan is a sheet material which first receives the printed code and then is applied to the pill/core at a later time. Therefore, the cited film of Sullivan, whether it is a thin plastic film or a protein-based film, is not a film coating as in the present invention.

2. Sullivan does not relate to film coating technologies

According to Sullivan, if the pills are non-coated tablets, or are otherwise porous and/or have a chalk-like exterior surface, a **"patch"** of a non-absorbent bio-compatible material is first (or simultaneously) applied to a **predetermined location** on the exterior surface of the pill. The code is then directly applied to the non-absorbent patch. (see 2nd Paragraph, Column 13, Sullivan).

Hence, Sullivan teaches the film is a pre-formed patch applied to a predetermined part of the surface of the pill instead of a coated film on the whole substrate. This is different from the film coating in the present invention. It is well known that film coating involves a coating enveloping the whole substrate. The difference is further demonstrated by Sullivan's teaching regarding uncoated pills, which is found in the last paragraph of column 11:

*“It (sic)[In] such instance, **a portion** of the outer surface of the uncoated tablet is sprayed (or otherwise coated) with a substance to aid in the printing onto the tablet or adhering to the tablet. The substance may be made from a material based on sugar, wax, gelatin, keratin, collagen, polymers or protein.”*

Therefore, Sullivan does not teach the core to be “film coated prior to the printed or etched marking being applied” as recited in Claim 1 or the step of “film coating said core” prior to applying a readable printed or etched covert marking as recited in Claim 14.

3. Nellhaus does not teach the limitation of “film coated” core either.

Nellhaus relates to a bar code schema for identification of solid form drugs, such as pills, tablets, capsules and the like by using a data matrix coding. It does not teach or suggest that the core be “film coated prior to the printed or etched marking being applied” either.

Further, Seigel and Cruttenden do not remedy the above deficiency in Nellhaus and/or Sullivan. Therefore, there is no teaching or suggestion of a covert marking on film coated core been given in any of the cited references. The differences between the claimed invention and the combination of the teachings of Nellhaus, Sullivan, Johnson and/or Seigel are not obvious to a person of ordinary skill in the art at the time the claimed invention was made, as required to maintain an obviousness rejection under 35 U.S.C. § 103(a). It is urged that the amended claims patentably distinguish over all of the 35 U.S.C. § 103 rejections made by the Examiner

Applicants respectfully submitted Claim 1 and Claim 14 are patentable over Nellhaus and/or Sullivan, stand alone or in combination. Claims 3-13 are dependent claims based on Claim 1 and claims 15-18 and 20-24 are directly or indirectly dependent on Claim 14. These dependent claims are patentable over the cited references as well.

D. Fees

No further fees are believed to be due. If, on the other hand, it is determined that further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.


E. Conclusion

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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